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Dockets Management Branch
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To Whom It May Concern:

In response to FDA dockets nos. 99D – *4488* and 99D – *4489* entitled *Guidance for Industry: Reducing Microbial Food Safety Hazards for Sprouted Seeds* and *Guidance for* Industry: *Sampling and Microbial Testing of Spent Irrigation Water During Sprout Production* (herein *Guidance),* I am disturbed about the rigidity of the proposed protocols. I represent a company which has developed a diagnostic kit for the detection of E. *coli* O157:H7 in spent irrigation water (effluent) and/or in a sample of sprouted seed. We are also developing a comparable kit used to detect *Salmonellae.* We have had extensive discussions with members of the National Center for Food Safety and Technology (NCFST), the International Sprout Growers Association (ISGA), and the USDA pertaining to the diagnostic kit's functional requirements and initial testing. We developed our kit to meet the needs of the industry keeping in mind the necessary sensitivity and specificity requirements to make a safe, effective, and accurate test kit. The E. *coli* sprout assay kit was introduced to the marketplace three months ago at the ISGA annual meeting in New Orleans, LA. The kit was well received, since our kit is self-contained, does not require any large microbiological equipment (e.g. incubators, media), and procures results within the sprout growth period.

However, *since the* release of this *Guidance* our sales have dropped precipitously. Only two test kits for each designated pathogen have been FDA-recommended. No ample explanation has been given as to why these particular kits are endorsed while the application of alternative assays would be considered unsanitary. How does a detection kit become permitted for usage under these conditions? What kind of study would have to be conducted to satisfy the FDA's definition of "sanitary". In paragraph two in the section titled Microbial Testing from docket 99D – 4488, screening methods "should first be validated either by formal collaborative studies or by comparative studies." Must this collaborative or comparative study be in conjunction with only the FDA or can the USDA, an academic institution, or a qualified food-testing laboratory play a role? AOAC International has approved all the suggested testing methods. Is this a necessary (albeit expensive) step towards FDA recognition and approval? Instead of an independent lab doing the pathogen screening, can individuals from a particular sprouting company become certified for performing in-house QA testing?

Sending out samples to be evaluated by an independent laboratory lends itself to another problem: time constraints. Even though the growth cycle for sprouted seed is four to five days, the extended time needed to get results back from an outside laboratory increases the chances of shipping out product before the results have been returned and examined. For the sprouter, recalling a shipment from the market is costly both in money and reputation. If a recall is necessary the expense to the producer is much higher than if the recall was avoided. But, take note; the sprouter must ship that product at its optimal growth point to distribute a quality product. It is not unreasonable to think that a producer may have shipped sprouts or effluent to a laboratory which has fallen behind on processing the provided sample(s). The sprouter, who has complied with the FDA's rulings, may consider the lack of response from the lab to imply that the data gathered from assaying the shipped samples yielded a negative result and the independent laboratory has not had the opportunity to relay the results. In fact this may not be the case. The lab merely has not investigated that

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sample for the possibility of contamination. The producer may then, at risk to public safety, ship the untested sprouts. By utilizing the rapid assays in-house, the sprout producer can have the assurance that there is not a problem with contamination. Further, these rapid assays are quick and easy to perform properly and will yield results early in the growth cycle. Since these test kits err on the side of false positive *(i.e.* 0% false negative with proper enrichment), if there is a questionable or positive result given by a rapid test kit an additional sample can be obtained and sent to an independent laboratory for testing and confirmation.

If the sprouting company can only have screening performed by an outside laboratory, those companies who make new and innovative test kits will have to compete with the already established (and now FDA endorsed) diagnostic companies for usage by the few food testing laboratories. This *Guidance* document "germinates" an unnatural oligopolistic 'microeconomy in which only two companies (Neogen and Biocontrol) are vying for total market share within the industry. This may lead to stagnation of product innovation and price gauging and/or price discrimination. The FDA is coercing the consumer to utilize one of these kits under penalty of producing food "adulterated under the act (section 402(a)(4) (21 U.S.C. 342(a)(4)))" or be subjected to "enforcement actions." This being the case, diagnostic companies will not expend the time nor the money to develop an alternative pathogen testing kit which will not yield a significant financial return on their initial investment. This is extraordinarily unfortunate if the idea and mechanism behind a new kit is superior to the current methods of detection.

The goal of *this Guidance* is to protect the public from potentially harmful pathogens that can and do proliferate within the sprout milieu. At the same time, this low-revenue industry is subservient to the contents of this document. The financial burden of having samples shipped daily to an outside lab may extirpate individual sprouting firms from the industry. Some of these firms are not located in an area easily accessible to a food safety laboratory and, therefore, would have to ship their samples far from their origin. This will introduce many unknown sources of error. For example, the temperature conditions subjected to the package containing the sample are variable and uncontrolled. Temperature extremes may enhance or inhibit the growth of all or some of the bacteria thereby biasing assay results. With in-house testing, these extra variables would be controlled and would then yield a result inherently more trustworthy than from a shipped sample. Also, rapid assays are convenient, easy to perform, and less expensive than an outside laboratory performing the testing. One does not have to have a doctorate in microbiology to execute these assays and this ease-of-use will make a sprout producer more inclined to be compliant *with* the *Guidance* docket. The public health would be better served by the increased compliance with the rapid kits than with the increasingly expensive outside laboratory suggestion. Occasional testing outside the sprouting firm is recommended and welcomed but daily, outside testing will place an undue burden on the wallets and minds of those who grow the sprouts.

Thank you,

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